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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,750

09/23/2003

Victor E. Kimball

11242/320

1782

34205

7590

12/10/2007

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,750	Applicant(s) KIMBALL ET AL.	
	Examiner Robert L. Nasser	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23-38 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-36 is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-32, 37-38, 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/2007 has been entered.

Before applying art, the examiner notes that the positioning means of claims 1 and 61 fail the 3 part test for a means plus function clause, set forth in MPEP 2181 I, because it has structure capable of doing the function. As such, the examiner will not invoke 35 USC 112, sixth paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21, 23-29, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al 4538618. With respect to claim 1, Rosenberg has a blood flow sensor, i.e. fiber 16, located in a measuring head 2 and an indicator 36, for indicating the blood flow measurement. The device further includes a PCO₂ sensor

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(see column 5, line 55). It is the examiners position that there would also be an indicator for indicating the PCO₂ measurement, given that the reference provides an indicator for all of the other measured values. The examiner notes that In Rosenberg, element 4 or element 26 both are devices that are capable of being used to hold the sensor in position adjacent a mucosal surface. As such, elements 4 and 26 are holder members. Both of elements 4 and 26 have a passageway through which the blood flow sensor extends, so that it extends outside of the holder. The examiner notes that it is capable of meeting the use where the device is held at element 26 and the sensor 16 is positioned in contact with the digestive system of the patient. Hence, it meets the claim language. Rosenberg meets the intended function of the positioning means and meets the claim limitation. Claims 2-21 are rejected in that the device is capable of being positioned adjacent any of the mucosal surfaces recited. With respect to claims 23-27, in order to meet the claim language, the reference need only have a structure that is capable of performing that function. In Rosenberg, element 4 or element 26 both are devices that are capable of being used to hold the sensor in position adjacent a mucosal surface. As such, Rosenberg meets the intended function of the positioning means and meets the claim limitation. With respect to claims 28 and 29, the flow sensor is laser-doppler or ultrasonic (see column 5, lines 43-50). Claim 38 is rejected for the reasons given above, noting that elements 26 and 4 are both at least partially flexible.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 37, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Riccitelli et al 5166990. Riccitelli et al further teaches that it is known to monitor pH and PCO₂ in the same intravascular measuring device. As such, it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Boggett et al WO 98/20794. Boggett et al further teaches that in a microvascular monitoring device like that of Rosenberg, that it is known to monitor the rate of change of blood flow. As such, it would have been obvious to modify Rosenberg to include a rate of change of flow determining device, to provide a more complete picture of the patient's condition.

Claims 33-36 are allowable in that none of the art has the holder with an inner portion having a shape corresponding to the shape under the tongue, as claimed. The examiner notes that Weil 6055447 and 6126024 show the holder with a sensor for measuring perfusion, i.e. blood flow. However, the current application claims priority to both of those patents, and those patents support the current claims. As such, those patents are not usable against the current invention.

Applicant's arguments filed 9/24/2007 have been fully considered but they are not persuasive.

Applicant has asserted that Rosenberg does not teach a device for assessing the degree of systemic perfusion including a flow sensor means and a holder with a passage to receive the flow sensor means, where the flow sensor means is engagable with a mucosal surface. The examiner disagrees. Rosenberg has a flow sensor, fiber 16, which extends through a passageway in holder 26 or 4 and is exposed. It is therefore engagable with any surface, including the mucosal surface.

Applicant has also asserted that Rosenberg has no element with similar structure to the positioning means are capable of performing a similar function. The examiner disagrees, noting that either element 4 or 26 is capable of performing the function of positioning the device relative to a mucosal surface.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
December 10, 2007